

REMARKS

Claims 1, 3, 6-8, 10, 13-14, 16-17, and 19-21 are pending in the application. In response to the Advisory Action mailed on July 31, 2003, claims 1 and 8 have been amended.

On September 8, 2003, Applicants' representatives participated in a telephone interview with the Examiner to determine whether the amended claims presented above are allowable. In the interview, the Examiner identified three references that she believed would anticipate or render obvious both the pending claims and the proposed amended claims. Applicants traverse.

The invention is not anticipated or obvious over the documents cited by the Examiner in the interview (U.S. Patent Nos. 5,750,651; 5,972,368; and 6,586,388). None of the patents, alone or in combination, teach or suggest a method for treating cartilage damage by administering an osteochondral graft.

U.S. Patent No. 5,972,368 ('368 patent) describes a deactivated bone graft in combination with bone morphogenetic proteins. It does not describe or suggest an osteochondral graft and does not indicate that the deactivated bone grafts it does describe would be useful for the regeneration of articular cartilage. Therefore, the '368 patent cannot render Applicants' invention anticipated or obvious.

U.S. Patent No. 5,750,651 ('651 patent) describes the combination of BMPs with a variety of matrices, made of synthetic materials or demineralized bone, for implantation into bone. In no way do these matrices resemble an osteochondral graft. Additionally, the '651 patent does not teach or suggest that these BMP-coated matrices

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would be useful for regenerating articular cartilage. Therefore, Applicants' invention cannot be rendered anticipated or obvious by the '651 patent.

U.S. Patent No. 5,586,388 ('388 patent) a member of the same patent family as the '651 patent, also describes the combination of BMPs with carrier matrices. These matrices are composed of demineralized bone or synthetic materials. The '388 patent does not describe or suggest the osteochondral grafts of Applicants' invention. Therefore, it cannot render the invention anticipated or obvious.

Claims 1, 3, 6-8, 13-14, 16-17, and 19-21 stand rejected as allegedly obvious over Hattersley and Pachence under 35 U.S.C. § 103(a). Applicants acknowledge that they inadvertently omitted claim 3 from arguments in the response to the Office Action mailed January 23, 2003, and respectfully request that all arguments regarding obviousness set forth in that response be applied to claim 3 as well.

The amended claims now recites methods and compositions for regenerating articular cartilage using an osteochondral graft treated with a composition consisting essentially of at least one BMP. Hattersley does not teach osteochondral grafts. Furthermore, it does not suggest that BMPs can be used with the osteochondral graft without PTHrP for regeneration of articular cartilage.

To establish a prima facie case of obviousness with a combination of references, it is not enough to establish that the two references, if combined, would anticipate the claims. Neither Hattersley nor Pachence anticipate the invention, and the requirement of the presence of PTHrP in the compositions of Hattersley prevent their combination from rendering the pending claims obvious because, as stated in Applicants' last response, it is well accepted that the omission of an element and retention of its function

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is an indication of unobviousness. *In re Edge*, 359 F.2d 896 (CCPA 1966); Manual for Patent Examining Procedure (2144.04).

The Examiner contends that one skilled in the art would be motivated to combine the teachings of Pachence and Hattersley with a high expectation of success as Hattersley allegedly teaches that BMP regulates bone and other tissue repair processes and Pachence allegedly teaches that osteochondral grafts can repair articular cartilage. Applicants disagree. The art must provide a perception of the problem to be solved by combination of the references. *Winner International Royalty Corporation v. Ching-Rong Wang*, 202 F.2d 1340 (Fed. Cir. 2000) (holding that the introduction of a ratcheting mechanism in a lock was not obvious over the disclosure that the mechanism was more convenient in a first reference, because there was no suggestion in the second reference that the original lock mechanism was not convenient enough). Pachence does not suggest any deficiency in its suggested solution to the problem of repairing articular cartilage. Similarly, Hattersley does not teach that the BMPs and PTHrP described therein, were not sufficient to solve the proposed problem. Without any perception of additional problems to be solved by the combination of the references, their combination is inappropriate.

The teachings of Pachence do not provide one skilled in the art with any reason to add a growth factor to the osteochondral grafts very briefly described in that specification. Even if there was a suggestion of the addition of growth factors, there is no suggestion that BMPs would be useful in the compositions of Pachence. Given the teachings of Pachence, one would have no reason to believe that BMPs would work in the disclosed osteochondral grafts.

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Additionally, Hattersley provides no suggestion or motivation to add its compositions to an osteochondral graft to regenerate cartilage. It also provides no suggestion to remove the PTHrP from its compositions. Therefore, Hattersley provides no suggestion of the continuing problem of regenerating articular cartilage that was solved by Applicants' invention of the combination of BMPs and osteochondral grafts. Accordingly, with no motivation to combine Hattersley and Pachence, there can be no prima facie case of obviousness and the rejection of the pending claims under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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